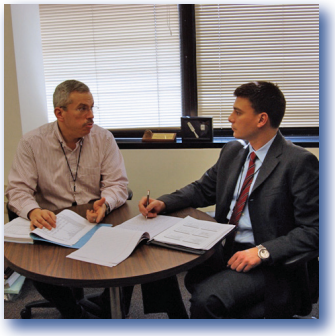
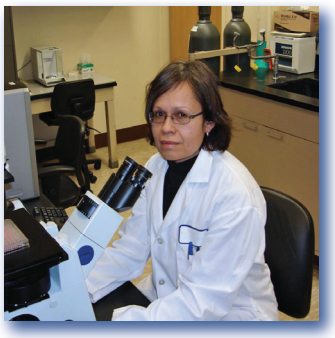
FDA Food and Drug Administration

COMMISSIONER'S

Fellowship Program

Protecting Public Health
Through Science and Regulation





FDA MISSION

The FDA is responsible for protecting the public health by assuring the safety, efficacy, and security of human and veterinary drugs, biological products, medical devices, our Nation's food supply, cosmetics, and products that emit radiation. The FDA is also responsible for advancing the public health by helping to speed innovations that make medicines and foods more effective, safer, and more affordable; and helping the public get the accurate, science-based information they need to use medicines and foods to improve their health.

For more information on the FDA, visit www.fda.gov.

PROGRAM OVERVIEW

The two-year Commissioner's Fellowship Program provides an opportunity for health professionals and scientists to receive training and experience at the FDA. Fellows will train at FDA's new state-of-the-art White Oak campus in Silver Spring, Maryland or at other FDA facilities.

The objective of the Commissioner's Fellowship Program is to train a cadre of highly accomplished scientists intensively in FDA regulatory science across devices, drugs, biologics, foods, and cosmetics. In addition to classes in each FDA product area, Fellows will receive instruction in FDA law, policy and international activities, federal budget process, networking and leadership skills, communications with the public and press, biostatistics, epidemiology, clinical trial design, risk assessment and risk management, and extensive case-based learning classes.

In parallel with this didactic training, the Fellows, with the guidance of their senior scientist Preceptor, will engage in a carefully designed and articulated FDA regulatory science project. FDA Centers, the Office of the Commissioner, and the Office of Regulatory Affairs have identified specific mission-critical research projects, which are posted on the Commissioner's Fellowship Program website. As part of the application process, applicants must identify projects of interest. Research projects are assigned to Fellows after an interview period with potential Preceptors. Each year new projects will be posted.

The FDA expects to retain many Fellows from each class, however, there are no guaranteed positions. Fellows not remaining with the FDA will be well-qualified for employment in industry or academia where the knowledge and perspective they gained at FDA will prove invaluable.

"What appealed to me most about the fellowship program was the opportunity to learn about regulatory science and participate in public health initiatives for children. As a pediatrician, I came from the clinical side of healthcare and was eager to apply my experience to the broader public health arena."

Francesca Dolcimascolo, M.D.
Class of 2008

COURSEWORK OVERVIEW

The Commissioner's Fellowship Program combines graduate level coursework designed to provide an in-depth understanding of the science behind regulatory review and a hypothesis-driven research project on a specific aspect of regulatory science.

Year 1

Semester 1 (October – December)

The first semester presents many short introductory courses that examine core FDA functions. Fellows will spend about 40% of their time completing these courses.

Coursework:
1. FDA and Public Policy
2. FDA Law
3. Negotiation and Influencing
4. Communication with the Public and Press
5. Ethics and Decision Making
6. Budgets and Operations
7. Beyond Our Borders
8. Conflict Management Skills
9. Briefing the Boss: Presenting to Senior Executives
10. Building Leadership Credibility

Research:
During this semester each Fellow will work with his or her Preceptor to develop a written research proposal that includes detailed literature review, methods to be used, anticipated outcomes, and skills and techniques to be acquired. During this time, work on the project can begin, even as the formal proposal is developed. The proposal should highlight how the Fellow anticipates the coursework will complement the Fellow's scientific experience.

Semester 2 (January – June)

Coursework:
1. Statistical Methods and Applications
2. Population Science/ Epidemiology
3. Clinical Trial Design and Evaluation

Research:
Students will spend about 65% of their time focusing on the graduate level coursework.

Summer Session 1 (July – August)

Coursework:
1. Investors View of Drug Development: An MBA Course

Research:
Fellows will spend 60% of their time conducting research relevant to their final projects.

"The Commissioner's Fellowship program creates a unique environment which allows for the development of crucial skills and acquisition of pertinent knowledge that, in turn, guides our understanding and appreciation of the intricacies of FDA regulatory science and its relationship to protecting public health."

Uros V. Djekic, Ph.D.
Class of 2008

"The Commissioner's Fellowship Program provides broad exposure to many aspects of regulatory science, while still affording me significant time to pursue my research interests in bioethics. It's a combination that I don't think I could get elsewhere."

John Rossi, V.M.D., M.Be.
Class of 2008

"The agency sees us as valuable assets and a gateway to its success."

Juandria V. Williams, Ph.D.
Class of 2008

Year 2

Semester 3 (September – December)

Coursework:
These courses describe the core functions and science of the Centers/Offices and will be taught by the respective Centers/Offices.

1. Devices and Radiological Health
2. Foundations of Toxicology
3. Understanding Biologic Agents and Their Evaluation
4. Understanding Drugs and Their Evaluation
5. Food and Nutrition Safety
6. Surveillance and Operations
7. Animal and Human Health: An Inseparable Link
8. Inside the Office of the Commissioner

Research:
Approximately 70% of the Fellows' time will be spent on their research project. Fellows will give formal research presentations to the Fellowship Committee, other Fellows, and Preceptors for presentation style critiques and feedback.

Semester 4 (January – June)

Coursework:
1. Process Control Engineering and Chemistry
2. Case Studies in Translational and Regulatory Science
3. Risk Assessment / Risk Management
4. Elective

Research:
Approximately 70% of the Fellows' time will be spent on their research project in preparation for the final presentation.

Summer Session 2 (July - October)

The Fellowship ends in October with final presentations of research results to Preceptors, Fellows, and Center staff. In the months leading up to the final presentation, Fellows are expected to focus on finalizing their projects and presentations.

Please note that all courses will be taught at the White Oak Campus in Silver Spring, Maryland. Remote access will be provided for Fellows at NCTR or other FDA locations.

All courses are instructed at the graduate level, and may require commitment outside of the traditional work schedule.

Who is eligible to apply?

Applicants must have a Doctoral level degree (M.D., D.O., D.V.M., D.D.S., D.P.M., Pharm. D., or Ph.D.) to be eligible. Applicants with a Bachelor's degree in an engineering discipline may also apply.

Applicants must be a U.S. Citizen, a non-citizen national of the U.S., or have been admitted to the U.S. for permanent residence before the program start date. Applicants cannot be current FDA employees, FDA contractors, or Commissioned Officers of the U.S. Public Health Service.

How do I apply?

Please visit the FDA Commissioner's Fellowship Program website: http://www.fda.gov/CommissionersFellowshipProgram.

What salary and benefits can I expect?

Salaries are extremely competitive and commensurate with education and experience. Additional funds are provided for education, travel, and research project expenses.

Fellows are hired as FDA employees, and therefore are eligible for all Federal employee benefits, including health insurance, retirement, and paid vacation. For more information on benefits, please visit: http://www.hhs.gov/careers/pay/index.html.

As an FDA employee, Fellows will be subject to all of the Agency's conflict of interest and ethics rules.

Questions or comments?

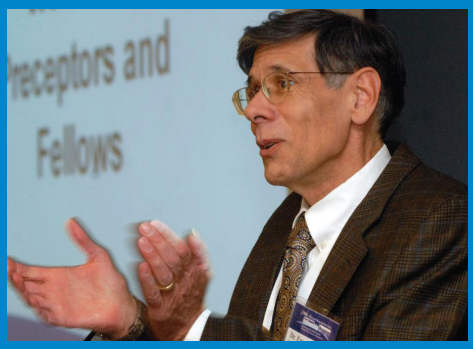
Email us at: fdacommissionersfellows@fda.hhs.gov

"The Commissioner's Fellowship provides a hands-on approach to understanding the inner workings of FDA regulatory science and policy. This invaluable experience allows me to gain specific knowledge regarding the protection of human subjects in international clinical trials."

Lester "Jao" Lacorte, M.D.
Class of 2008

"I am very appreciative of the congenial and encouraging work environment where I can share my thoughts and contribute to the team effort."

Paramjeet Kaur, Ph.D.
Class of 2008



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